CLUSIONS: Classical test theory-based psychometric methods generally supported the CES-D scale as an outcome measure of depression after stroke. DIF on some items suggests that symptoms experienced in post-stroke depression may differ from depression in the general population.

PMH74

COMPARING PSYCHOMETRIC PROPERTIES OF SELF-VERSUS INTERVIEWER-RATED INSTRUMENTS USED IN CLINICAL TRIALS FOR PATIENTS WITH ANXIETY DISORDERS

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Clinical trials often employ self-rated and interviewer-rated instruments to assess the effectiveness of anxiolytic treatments. Understanding potential differences in these scales and their psychometric properties therefore is important for interpreting trial results. **OBJECTIVES:** Identify and critique key methods used to compare psychometric properties of self-versus interviewer-rated instruments in clinical trials for patients with anxiety disorders. **METHODS:** A literature review focusing on anxiety outcome assessments used in clinical trials was conducted in Medline, OLGA, and PsychINFO databases of articles published before September 2003. This study included only articles that were published in English and reported data from clinical trials with anxiolytic drugs. **RESULTS:** From the literature review, two commonly used instruments included the self-rated Symptom Checklist-90, and the interviewer-rated Hamilton Rating Scale for Anxiety. Five methodological approaches were identified: 1) precision of measurement: means and variances of instrument scores; 2) construct validity: comparison of underlying constructs for each instrument using factor analysis; 3) internal consistency: homogeneity of items within the same domain of an instrument; 4) instrument sensitivity: ability of the instrument to detect treatment effect by differentiating control from treatment groups or between groups of different disease states; and 5) instrument responsiveness: ability of each instrument to detect minimal clinically important changes within patients over time (pre-and post-treatment phases) using distribution-based and anchor-based approaches. Tests for statistical and clinical significances in score changes are discussed. For each of the five approaches, suggested statistical methods and examples from the literature are presented. **CONCLUSIONS:** The structured taxonomy developed in this study will help interpret clinical trial results that use self-rated and interviewer-rated instruments, as well as elucidate potential methods for developing and validating new instruments to assess the effectiveness of anxiolytic treatments in trials.

PMH75

DEVELOPMENT OF A PATIENT-REPORTED INSTRUMENT TO ASSESS THE FUNCTIONAL STATUS OF PATIENTS WITH BIPOLAR DISORDER

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OBJECTIVES: Bipolar disorder, as well as some of the pharmacological agents used to treat it, often impairs patients' ability to function on a day-to-day basis. The goal of the present study was to develop a sensitive, psychometrically sound self-report instrument that would help to identify treatments effective in maximizing the functional status of bipolar patients. **METHODS:** Through consultation with key opinion leaders, literature review, and individual in-depth interviews with bipolar patients, the team developed a questionnaire using 50 items to address the following domains: cognitive functioning, sleep, role functioning, emotional functioning, energy/vitality, social functioning, personal management, and sexual functioning. The draft questionnaire was then tested and revised through 2 iterative sets of cognitive interviews with 19 additional patients in multiple locations. **RESULTS:** In general, the pretest participants deemed the set of constructs addressed in the questionnaire to be both comprehensive and representative of their daily functioning. They also reported that the final set of items was easy to comprehend and to fill in, noting that the 7-point Likert-type response scale seemed optimal; the points on the scale appeared to represent the full spectrum of answer choices, yet participants could easily distinguish between the options. Cognitive testing also resulted in the elimination of 17 items, which were either deemed inessential to the measurement of functional status, applicable only to a subset of patients (eg, family responsibilities), or too similar in content to other items. **CONCLUSIONS:** The resulting questionnaire addresses all constructs considered central to the functional status of patients with bipolar disorder, with 33 items that are phrased to facilitate patient comprehension and completion. A multisite, 600-patient validation study is currently under way to evaluate the psychometric properties of this instrument.

PMH76

A COMPREHENSIVE RETROSPECTIVE STUDY OF ASSOCIATIONS BETWEEN DIABETES AND TREATMENT WITH RISPERIDONE, OLANZAPINE, QUETIAPINE, AND CONVENTIONAL ANTIPSYCHOTICS

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OBJECTIVES: The potential for antipsychotic-induced diabetes is an important issue. Retrospective studies using large patient databases have had conflicting findings regarding diabetes risks associated with different antipsychotics. **METHODS:** Claims data for thousands of psychosis patients treated or untreated with antipsychotics were analyzed. Screening for preexisting diabetes, identification of diabetes with prescription claims only, and requirement of antipsychotic monotherapy provide better control for confounding influences and represent a stronger study design. Diabetes odds ratios for risperidone, olanzapine, quetiapine, or conventional antipsychotics versus non-treatment were estimated for all patients and for patients stratified by dose levels. Logistic regression controlled for age, sex, type of psychosis, length of observation/treatment, preexisting excess weight, and use of other drugs with diabetogenic effects. **RESULTS:** Under a weaker study design, all of the antipsychotics were associated with significantly higher odds of diabetes relative to non-treatment. Odds ratios (95% confidence intervals [CI]) were: risperidone 1.388 (1.276–1.509), olanzapine 1.331 (1.224–1.446), quetiapine 1.394 (1.247–1.559), and conventional antipsychotics 1.365 (1.238–1.503). Under a stronger study design, relative odds for risperidone and quetiapine declined, becoming statistically insignificant, whereas odds for olanzapine and conventional antipsychotics increased. Odds ratios (95% CI) were: risperidone 1.224 (0.962–1.562), olanzapine 1.858 (1.549–2.238), quetiapine 1.087 (0.742–1.612), and conventional antipsychotics 1.755 (1.381–2.221). With quetiapine, odds of diabetes were not significantly increased at any dose level relative to non-treatment. Odds were significantly increased